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10/721,115	11/24/2003	John G. Sotos	APN-001	6156

7590  
Kenneth M. Kaslow  
c/o Apneos Corporation  
#41  
2033 Ralston Ave.  
Belmont, CA 94002

09/25/2007

EXAMINER
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MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3735

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09/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/721,115	Applicant(s) SOTOS ET AL.	
	Examiner Patricia C. Mallari	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 12-14, 21, 25, 30, 32, 36, 49 and 51-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-14, 21, 25, 30, 32, 36, 49, 51-53 and 55-73 is/are rejected.
- 7) ☒ Claim(s) 54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/23/07 has been entered.

### ***Drawings***

The drawings were received on 7/10/06. These drawings are not acceptable because they contain new matter. See "Response to Amendment" below.

### ***Response to Amendment***

The amendment filed 8/23/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "The output(s) 92 of one or more sensors 91, e.g. tracheal vibration sensor or position sensor, is (are) coupled to a transmitter 94 . . . Thus it is possible to couple one or more sensor 91 to a conversion means 99 without a physical connection between them". The specification as originally filed contained a claim stating "wireless transmitting the tracheal vibration information

and information indicative of the orientation of the portion of the patient's body from the sensing means to a recording device containing a memory before the step of converting the data into digital data". However, the original specification did not state that either the tracheal vibration sensor or the position sensor may be coupled to the transmitter. Rather the recited portion of the original specification indicates that both the vibration sensor and the position sensor are coupled to the transmitter.

The drawings filed 7/10/06 include figure 9 that shows "Sensor(s)" coupled to the transmitter. Again, the inclusion of only one sensor being coupled to the transmitter is considered new matter which is not supported by the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Objections***

Claim 14 is objected to because of the following informalities:

Claim 14 recites, "the means for approximately simultaneously coupling further comprises an adhesive material coupled to a portion of the housing." Claim 13, upon which claim 14 depends, recites, "the means for approximately simultaneously coupling further comprises means for coupling the housing to the portion of the patient's body". The language in claim 13 invokes 35 U.S.C. 112, 6<sup>th</sup> paragraph (see the rejection below), wherein the corresponding structure described in the applicants' specification appears to be adhesive coupled to a portion of the housing. Therefore, claim 14 appears to result in a housing having two sets of adhesive. In accordance with the applicants' specification, it appears that "the means for approximately simultaneously

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coupling further comprises" should be replaced with "means for coupling the housing to the portion of the patient's body comprises". Failure to correct this problem could result in a rejection under 35 U.S.C. 112, 1<sup>st</sup> paragraph for lack of written description.

Appropriate correction is required.

Claims 36, 62, and 63 are objected to because of the following informalities:

On line 2 of claim 36, "further" should be deleted.

On line 2 of claim 62, "further" should be deleted.

On line 2 of claim 63, "further" should be deleted. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 71 and 72 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 71 recites, "the position sensor is coupled to an axial portion of the body of the patient". The human body, or portion thereof is non-statutory subject matter and cannot positively be claimed. Applicants might overcome this rejection by replacing "is coupled" to "is adapted to be coupled".

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 62, 63, 66, and 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 62 recites, "wherein at least one of the first or second information transmission means further comprises means for electrical transmission of information". Claim 63 recites, "wherein at least one of the first or second information transmission means further comprises means for wireless transmission of information". The specification describes a means for electrical transmission of information in the form of a cable containing one or more wires bring the information from the housing 12 and thus from vibration sensor 14 and position sensor 16 to the recording device (see p. 19 of the specification). The specification further describes that information can be wirelessly transmitted from the housing to the recording device. However, there is no description of an embodiment in which only one of the first and second transmitting means for transmitting information comprises means for electrical transmission information. Similarly, there is no description of an embodiment wherein the vibration sensor and the position sensor each further comprise separate information transmitting means for transmitting information, wherein at least one of both of such means for transmitting information comprise means for wireless transmission of information.

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Claim 66 recites "means for converting tracheal information into digital data with a sampling rate of at least approximately 1900 hertz". The specification lacks written description of a sampling rate of at least approximately 1900 hertz as claimed. Page 18 of the specification states, "the sampling rate must be at least 2 KHz", but no portion of the specification specifically recites "at least approximately 1900 hertz".

Claim 70 recites, "sampling rate of at least approximately 2000 hertz". The specification lacks written support for at least *approximately* 2000 hertz, and only describes the sampling rate as at least 2kHz or 2000 Hz.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 12-14, 21, 30, 32, 36, 55, 56, 59-62, 64, 65, 69, 71, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 2002/0165462 to Westbrook et al. Westbrook teaches a system for monitoring a patient comprising a vibration sensor 32, wherein a microphone is a vibration sensor, a position sensor 36 that changes state depending upon its orientation with respect to the earth's gravity, and

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a housing containing the vibration and position sensor and adapted to be coupled to the patient (see entire document, especially figs. 2-5,7, and 8; paragraphs 58, 59, 69, and 70).

As to the language "for collecting tracheal vibration information from the patient", the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Westbrook teaches all of the claimed structural limitations and their recited relationships. The vibration sensor or microphone of Westbrook is certainly capable of use to collect tracheal vibration information, wherein the type of vibration information collected is merely a result of the placement of the sensor.

Regarding claim 2, the vibration sensor comprises a microphone (see entire document, especially paragraph 69 of Westbrook).

Regarding claim 3, the positions sensor comprises an accelerometer (see entire document, especially paragraphs 58 and 70 of Westbrook).

Regarding claim 12, "means for approximately simultaneously coupling at least a portion of the vibration sensor and a portion of the position sensor to a portion of the patient's body . . ." meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. An example of the corresponding structure set forth in the applicants' disclosure appears to be adhesive. Westbrook teaches the system including adhesive 56, wherein the adhesive is used to couple the system to the patient's body (see entire document, especially paragraph 61 of Westbrook).



Regarding claims 13 and 14, "the means for coupling the housing to the portion of the patient's body" meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. An example of the corresponding structure set forth in the applicants' disclosure appears to be adhesive applied to the housing. Westbrook teaches the system including adhesive 56 applied to the housing 54 (see entire document, especially paragraph 61 of Westbrook).

Regarding claim 21, the system further comprises a memory 44, a conversion means for receiving the tracheal vibration information and converting it into digital data 40, and a means for writing the digital data into the memory (see entire document, especially fig. 2; paragraphs 58, 62, 73, and 74 of Westbrook). The language "conversion means for receiving the tracheal vibration information and converting it into digital data" and "means for writing the digital data into the memory" meet the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. The corresponding structures to the "conversion means" in the applicants' specification appear to be an A/D converter. Westbrook describes an A/D converter 40 (see paragraph 58 of Westbrook). The applicants describe the corresponding structure for the "means for writing the digital data into the memory" as merely "writing means 83". While the writing means 83 is not explicitly described, it is understood to merely be a processor, controller, or portion of a processing unit. Westbrook describes a microcontroller writing the digital data to the memory (see entire document, especially paragraph 73 of Westbrook).

Regarding claim 30, the language "indicator means . . . for informing a user of the preferred orientation the housing is to have when coupled to the patient" meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. The corresponding structure in the applicants' specification appears to be any characteristic of the housing that indicates orientation, such as a shape property of a portion of the housing (see p. 17 of the applicants' specification). Westbrook teaches a shape property of the housing, which shape indicates an orientation of the device when applied to the body (see entire document, especially paragraph 60 of Westbrook).

Regarding claims 32, 36, 55, 56, and 59 Westbrook describes coupling the vibration sensor and the position sensor to a portion of the patient's body (see entire document, especially figs. 2, 7; paragraphs 59-61 of Westbrook), wherein coupling the enclosure 54 to the body comprises coupling both the vibration sensor and the position sensor to the body portion.

Regarding claim 36, the step of coupling the vibration sensor further comprises coupling a microphone to the patient (see entire document, especially paragraphs 58 and 69 of Westbrook).

Regarding claim 55, the coupling of the vibration sensor and the coupling of the position sensor to the body are approximately simultaneous (see entire document, especially figs. 2, 7; paragraphs 59-61 of Westbrook), since the enclosure 54 houses both sensors, and the enclosure as a whole is coupled to the body.

Regarding claim 56, a vibration transducer (microphone) is provided as part of the vibration sensor and an acceleration transducer (accelerometer) is provided as part

of the position sensor, wherein the vibration transducer and acceleration transducers are coupled to the portion of the patient's body simultaneously, since both are housed in the enclosure, and the enclosure is coupled to the body (see entire document, especially figs. 2, 7; paragraphs 58-61, 69, and 71 of Westbrook).

Regarding claim 59, an indicator is coupled to the position sensor, wherein the indicator, for example, is the slight concavity of the enclosure to conform to the shape of the forehead (see entire document, especially paragraph 60 of Westbrook). The enclosure as a whole, and therefore the position sensor, is oriented with respect to the patient's body as indicated by the indicator (see entire document, especially figs. 7, 9; paragraphs 59 and 60 of Westbrook), wherein the description of the indicator and its function is clearly and implication that, when applied to the body, the enclosure is so oriented.

Regarding claims 60, 64, and 65, Westbrook discloses a system wherein the position sensor comprises an acceleration transducer adapted to be coupled to the patient substantially adjacent to the vibration transducer (see entire document, especially figs. 2, 3, 5, 7; paragraphs 58-61, 69, and 70 of Westbrook).

Regarding claims 61 and 62, the language "first information transmitting means for transmitting information representing the tracheal vibration information", "second information transmitting means for transmitting information representing the position of the patient", and "means for electrical transmission of information" fulfill the 3 prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. The corresponding structure in the applicants' specification appears to merely be wires (see

p. 19 of the applicants' specification). Westbrook shows in figure 2 information being transferred from each of the position sensor 36 and the microphone 32 to the recording device 44 and further describes all of the system components being mounted on a printed circuit board 62, wherein, clearly the circuit board operates as means for transmitting information. The circuit board of Westbrook is considered to be an equivalent to both of applicants' means for transmitting information because it performs the same function in substantially the same way and produces substantially the same result as the corresponding elements in the applicants' specification.

Regarding claim 64, a housing 54 contains the vibration transducer and the acceleration transducer (see entire document, especially figs. 2, 3, 5, 7; paragraph 59 of Westbrook).

Regarding claim 65, the system further comprises a recording means 44 (See entire document, especially paragraphs 58 and 75 of Westbrook). The language "recording means for recording data representing the tracheal vibration information" meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6h paragraph. The corresponding structure set forth in the specification appears to be a non-volatile memory, such as flash memory. Westbrook describes a memory, such a flash memory (see entire document, especially paragraphs 58 and 75 of Westbrook).

Regarding claim 69, the housing is adapted to be coupled to a peri-tracheal portion of the body of the patient (see entire document, especially fig. 7; paragraphs 59-61 of Westbrook), wherein the strap or adhesive on the enclosure would enable the housing to be attached to any part of the body.

Regarding claims 71 and 72, the position sensor is coupled to or adapted to be coupled to an axial portion of the body (see entire document, especially fig. 7 of Westbrook), wherein, in its broadest reasonable interpretation "axial" means "relating to or located on or around an axis", such that the position sensor provides information indicating that the axial portion of the patient's body is one of a plurality of predefined positions (see entire document, especially paragraph 71 of Westbrook).

With further regard to claim 72, the position sensor provides information indicating that the axial portion of the patient's body is in a substantially supine position (see entire document, especially paragraph 71 of Westbrook).

Claims 1, 3, 12, 13, 21, 25, 60, 64, 65, and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,949,075 to Hatlesad et al. Hatlesad teaches a system for monitoring a patient comprising a vibration sensor for collecting tracheal vibration information from the patient, a position sensor that changes state depending upon its orientation with respect to the earth's gravity, and a housing the vibration sensor and position sensor and adapted to be coupled to the patient (see entire document, especially col. 3, line 65-col. 4, line 11; col. 5, lines 1-65; col. 6, lines 1-20 of Hatlesad).

As to the language "for collecting tracheal vibration information form the patient" the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art of record, since Hatlesad teaches all of the claimed structural features and their recited relationships. The vibration sensor of

Hatlesad could certainly be used to collect tracheal vibration information, particularly since the vibration sensor is capable of detecting any type of vibration and the type of vibration information is merely a function of the placement of the sensor.

Regarding claim 3, the position sensor comprises an accelerometer (see entire document, especially col. 5, lines 5-25; col. 5, line 44-col. 6, line 20 of Hatlesad).

Regarding claims 12 and 13, "means for approximately simultaneously coupling at least a portion of the vibration sensor and a portion of the position sensor to a portion of the patient's body, such that the position sensor tracks changes in orientation of the portion of the patient's body to which the system is adapted to be coupled" and "means for coupling the housing to the portion of the patient's body" both meet the three prong analysis set forth in MPEP 2181, thereby, invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. An example of the corresponding structure in the applicants' specification for both "means plus function" language appears to merely be an implantable housing (see p. 17 of the applicants' specification). Hatlesad teaches the housing being implantable (see entire document, especially col. 4, lines 6-10 of Hatlesad).

Regarding claim 21, the system of Hatlesad further comprises a memory 34, conversion means 40, and means for writing the digital data into the memory. The language "conversion means for receiving the tracheal vibration information and converting it into digital data" and "means for writing the digital data into the memory" fulfills the 3-prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. The corresponding structure in the applicants' specification to the conversion means appears to merely be an analog to digital (A/D) converter. Hatlesad

teaches an A/D converter 40 (see entire document especially col. 4, lines 4-6 of Hatlesad). The corresponding structure in the applicants' specification to the "means for writing" is merely described as "writing means 83". While "writing means 83" is not explicitly described it is understood to be a processor, controller, or part of a processing unit. Hatlesad describes a controller 32 for writing the digital data to the memory (see entire document, especially fig. 1; col. 4, lines 40-57 of Hatlesad).

Regarding claim 25, the system further comprises a playback means (see entire document, especially col. 6, line 53-col. 7, line 12; col. 11, lines 43-60; col. 12, lines 6-16 of Hatlesad), wherein the playback means is capable of substantially recreating the collected tracheal vibration information from the digital data written into the memory.

Regarding claims 60, 64, and 65, Hatlesad further teaches the vibration sensor comprising a vibration transducer and the position sensor comprising an acceleration transducer adapted to be coupled to the patient substantially adjacent to the vibration transducer (see entire document, col. 5, line 5-col. 6, line 20 of Hatlesad).

With further regard to claim 64, a housing contains the vibration transducer and acceleration transducer (see entire document, especially col. 4, lines 5-10 of Hatlesad).

With further regard to claim 65, the language "recording means for recording data representing the tracheal vibration information" fulfills the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. The corresponding structure in the applicants' specification appears to merely be a non-volatile memory. Hatlesad describes a non-volatile memory (see entire document, especially col. 4, lines 40-57; col. 12, lines 6-16 of Hatlesad).

Regarding claim 71, the position sensor is coupled to an axial portion of the body, wherein, in its broadest reasonable interpretation "axial" means "relating to or located on or around an axis", such that the position sensor provides information indicating that the axial portion of the patient's body is one of a plurality of predefined positions (see entire document, especially col. 4, lines 5-10; col. 7, line 45-col. 8, line 5 of Hatlesad).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49, 53, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westbrook, as applied to claims 1-3, 12-14, 21, 30, 32, 36, 55, 56, 60, 61, 62, 64, 65, 69, 71, and 72 above, and further in view of US Patent No. 6,168,568 to Gavriely (herein referred to as Gavriely '568). Westbrook teaches providing a memory (see entire document, especially paragraphs 58, 75 of Westbrook), converting the information indicative of the orientation of the portion of the patient's body into digital data (see entire document, especially fig. 2; paragraph 58 of Westbrook), and writing the digital data into the memory (see entire document, especially paragraph 73 of Westbrook). Westbrook lacks converting the tracheal vibration information into digital



data, in that the reference is silent as to whether the information collected by the vibration sensor comprises tracheal vibration information.

However, Gavriely '568 discloses a system for analyzing apnea in a patient, wherein breath sounds are collected from a patient using a vibration sensor, the breath sounds including tracheal vibrations or sounds (see entire document, especially col.8, lines 36-50; col. 11, lines 5-20 of Gavriely '568). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the tracheal vibration of the patient, as taught in Gavriely '568 in the system and method of Westbrook, since Westbrook teaches acquiring breath sounds, and Gavriely '568 discloses tracheal vibrations or sounds as appropriate such breath sounds for respiratory analysis, to achieve the predictable result of acquiring and analyzing tracheal vibrations.

Regarding claim 53, the tracheal vibrations are acquired from a peri-tracheal position (see entire document, especially col. 11, lines 14-16 of Gavriely '568).

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westbrook, as applied to claims 1-3, 12-14, 21, 30, 32, 36, 55, 56, 59-62, 64, 65, 69, 71, and 72 above, in view of US Patent No. 6,514,218 to Yamamoto, and further in view of US Patent No. 6,432,061 to Nissilä. Westbrook, as modified, teaches transmitting the information to the recording device after digitizing the information rather than before, and further teaches a wired information transmission, rather than wireless transmission. However, Yamamoto teaches transmitting acquired vibration and position information to a recording device 8 having a memory 89 before converting the data into digital data

(see entire document, especially figs. 10 & 16; col. 11, lines 1-43 of Yamamoto).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the arrangement and order of information transfer of Yamamoto, in place of that of Westbrook, as modified, as it would merely be the substitution of one known arrangement of parts for another, wherein such arrangement fails to affect the ability of the system or method to detect and store detected information. Westbrook, as modified by Yamamoto, lacks a wireless transmission.

However, However, Nissilä discloses using either a wired or wireless connection between two components in a system (see entire document, especially figs. 1-3; col. 4, lines 1-32 of Nissilä). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to wirelessly transmit any information of Westbrook, as modified, since Nissilä shows wireless and wired transmissions to be functionally equivalent.

Claims 52 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westbrook, as applied to claims 1-3, 12-14, 21, 30, 32, 36, 55, 56, 59-62, 64, 65, 69, 71, and 72 above, and further in view of US Patent No. 6,432,061 to Nissilä et al. Westbrook teaches transmitting tracheal vibration and body portion orientation information to the recording device using a wired connection (see entire document, especially fig. 2, paragraphs 58-59 of Westbrook), wherein a circuit board is a wired connection, rather than wireless transmitting the information. However, Nissilä discloses using either a wired or wireless connection between two components in a system (see

entire document, especially figs. 1-3; col. 4, lines 1-32 of Nissilä). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to wirelessly transmit any information of Westbrook, since Nissilä shows wireless and wired transmissions to be functionally equivalent.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westbrook in view of Gavriely '568, as applied to claims 49, 53, 57 above, and further in view of US Patent No. 6,375,623 to Gavriely (herein referred to as Gavriely '623). Westbrook, as modified, teaches collecting and storing in a non-volatile memory the position and vibration information during at least a 6-hour time span and converting the tracheal vibration information into digital data using an A/D converter (see entire document, especially paragraphs 58, 75 of Westbrook). However, Gavriely '623 teaches a system for acquiring breath sounds, comprising an A/D converter for converting breath sound signals into digital signals, wherein the A/D converter has a 12 bit resolution and a sampling rate of 8000 to 15,000 Hz, such a sampling rate being at least approximately 2000 Hz (see entire document, especially col. 6, line 55-col. 7, line 7 of Gavriely '623). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the sampling rate and resolution of the A/D converter of Gavriely '623 as that of the A/D converter of Westbrook, as modified, since Westbrook, as modified teaches using an A/D converter and Gavriely '623 describes an appropriate sampling rate and resolution for such an A/D converter. Using the known

sampling rate and resolution of the A/D converter of Gavriely '623 in the system of Westbrook, as modified, would have been obvious to one of ordinary skill.

Claims 66, 68, 70, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westbrook, as applied to claims 1-3, 12-14, 21, 30, 32, 36, 55, 56, 59-62, 64, 65, 69, 71, and 72 above, and further in view of Gavriely '623. Westbrook teaches a means for storing the digital data accumulating during at least a 6 hour time span in a non-volatile memory (see entire document, especially paragraphs 58, 75 of Westbrook), wherein such a means appears to merely be a non-volatile memory capable of storing at least 6 hours worth of digital data. The language in claim 66, "means for converting tracheal vibration information into digital data with a sampling rate of at least approximately 1900 Hz and a resolution of at least 12 bits" fulfills the 3 prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. The corresponding structure in the applicants' specification appears to be merely an A/D converter, wherein such an A/D converter would have a sampling rate of at least 1900 Hz and a resolution of at least 12 bits. . Westbrook is silent as to the sampling rate and resolution of the A/D converter. However, Gavriely '623 teaches a system for acquiring breath sounds, comprising an A/D converter for converting breath sound signals into digital signals, wherein the A/D converter has a 12 bit resolution and a sampling rate of 8000 to 15,000 Hz, such a sampling rate being at least approximately 1900 Hz or at least 2 kHz (see entire document, especially col. 6, line 55-col. 7, line 7 of Gavriely '623). Therefore, it would have been obvious to one of ordinary skill in the art at the

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time of invention to use the sampling rate and resolution of the A/D converter of Gavriely '623 as that of the A/D converter of Westbrook, since Westbrook teaches using an A/D converter and Gavriely '623 describes an appropriate sampling rate and resolution for such an A/D converter. Using the known sampling rate and resolution of the A/D converter of Gavriely '623 in the system of Westbrook would have been obvious to one of ordinary skill.

Regarding claim 68, in claim 68, the language, "means for converting the tracheal vibration information into digital data . . ." fulfills the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. The corresponding structure in the applicants' specification appears to merely be an A/D converter having a sampling rate of at least 2 kHz (see pp. 12 and 18 of the applicants' specification). Westbrook, as modified, teaches the A/D converter having a sampling rate of 8000-11,500 Hz, which values are at least 2kHz (see entirety of both documents, especially col. 6, line 55-col. 7, line 7 of Gavriely '623).

Regarding claim 70, "means for converting the tracheal vibration information into digital data at a sampling rate of at least approximately 2000 hertz and with a resolution of at least 12 bits" fulfills the 3 prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. The corresponding structure in the applicants' specification appears to merely be an A/D converter having a sampling rate of at least 2000 Hz and a resolution of at least 12 bits. Westbrook, as modified, teaches an A/D converter having a sampling rate of at least 2000 Hz (11, 025 Hz or 8000-15000 Hz)

and a resolution of at least 12 bits (see entirety of both documents, especially col. 6, line 55-col. 7, line 7 of Gavriely '623).

Regarding claim 73, the language "means for converting the tracheal vibration information into digital data such that the digital data may be transformed by a playback means into sound . . ." meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. The corresponding structure in the applicants' specification appears to merely be an A/D converter having a sampling rate of at least 2 kHz (see pp. 12 and 18 of the applicants' specification). Westbrook, as modified, teaches the A/D converter having a sampling rate of 8000-11,500 Hz, which values are at least 2kHz (see entirety of both documents, especially col. 6, line 55-col. 7, line 7 of Gavriely '623).

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hatlesad, as applied to claims 1, 3, 12, 13, 21, 25, 60, 64, 65, and 71, above, and further in view of US Patent No. 5,443,907 to Mansy et al. Hatlesad teaches a playback means capable of substantially recreating the collected vibration information from the data representing the collected vibration information recorded by the recording means (see entire document, especially col. 6, line 54-col. 7, line 12; col. 11, lines 43-60 of Hatlesad), but is silent as to the frequency range of the playback means. However, Mansy describes a speaker 20 having a frequency range of 20 to 1600 Hz, which includes the range of 400 to 1000 Hz (see entire document, especially col. 8, lines 12-29 of Mansy). The speaker of Mansy would be capable of substantially recreating

collected tracheal vibration such that upon playback of the data a listener hears at least substantially the same sound that the listener would have heard through a listening device having a frequency response of at least approximately 400 to 1000 Hz in the same position of the vibration transducer at the time the tracheal vibration information was collected, wherein the applicants disclose that such a playback means would merely need to have a frequency range at least approximately equal to the frequency sensitivity range of the vibration sensor in order to reproduce all of the captured information per unit time (see pp.20-21 of the applicants' specification). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the speaker of Mansy as that of Hatlesad, since Hatlesad discloses using a speaker and Mansy describes an appropriate such speaker.

### ***Response to Arguments***

Applicant's arguments with respect to claims 11-3, 12-14, 21, 25, 30, 32, 36, 49, 51, and 52 have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

Claim 54 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Regarding claim 54, the primary reason for allowance is the inclusion of the

body portion being the suprasternal notch, in combination with all of the other limitations of the claim, which is not taught by the prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Patricia Mallari  
Patent Examiner  
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